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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Hang-Chiung LIN et al.	Confirmation No: 8466
Appl. No.	: 10/717,559	
Filed	: November 21, 2003	
Title	: PHARMACEUTICAL COMPOSITION FOR ENHANCING IMMUNITY, AND EXTRACT OF PORIA	
TC/A.U.	: 1617	
Examiner	: C.K. Huynh	
Docket No.:	: LINH3023/REF	
Customer No:	: 23364	

37 CFR § 41.41 REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
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Sir:

This reply brief is submitted in response to the Examiner's Answer mailed December 24, 2008, in connection with the above identified application. The Examiner's Answer contains a new ground of rejection and this reply replies to the new grounds of rejection. The previously filed appeal brief responds to grounds of rejection in the final rejection. It is believed that no fee is required for this reply brief, however, any fees necessary for this appeal may be charged to Deposit Account No. 02-0200.

The period for filing this reply brief is set to expire on February 24, 2009. This reply brief is timely filed.

41.37 (c)(1)(iii) STATUS OF THE CLAIMS

This application contains claims 1-23. Claims 1-5 and 14-23 have been canceled from the application without prejudice or disclaimer and are no longer pending. Claims 6-13 are pending and are the claims on appeal. Claims 6-13 stand finally rejected under 35 USC 103(a) as obvious over the prior art cited and applied in the Examiner's Answer and these claims are subject to new ground of rejection as indefinite under 35 USC 112, second paragraph.

41.37 (c)(1)(vi) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There is an obvious rejection to be reviewed of claims 6-13 under 35 U.S.C. 103(a) as being unpatentable as obvious over Takahashi et al. (JP 8-119864) in view of Tai et al. (Phytochemistry. 1995. Vol. 39, No. 5. pp. 1165-1169). This rejection was responded to in the Appeal Brief filed July 10, 2008

The Examiner's Answer contains a new ground of rejection of claims 6-13 under 35 U.S.C. 112, second paragraph as indefinite. This issue for review for the new grounds of rejection is whether the use of the terms "substantially" and "low" render claims 6-13 indefinite under 35 USC 112, second paragraph.

41.37 (c)(1)(viii) ARGUMENT

The term "substantially" in claim 6, line 3, is said to be a relative term which renders the claim indefinite. The term "substantially" is alleged as not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claim 6 states that the Poria extract must be "substantially devoid of secolanostane." The specification does not provide any definition or guidelines that could be used to determine what amounts of secolanostane could be present in the extract and still have the extract be considered "substantially devoid of secolanostane." Thus, an artisan of ordinary skill could not reasonably ascertain the metes and bounds of the claims. Claim 7-13 are indefinite in that they depend from claim 6 and do not clarify this §112, second paragraph issue. These statements have been carefully considered but are most respectfully traversed and this rejection should be withdrawn or reversed on appeal.

Substantially is a relative term as indicated in the new ground of rejection but it is most respectfully submitted that this term does not render claim 6 indefinite to one of ordinary skill in the art in light of the disclosure and the level of skill of one of ordinary skill in the art to which the invention pertains. This is also true with respect to claims 7-13. Applicants most respectfully submit that the term "substantially" as used in the context of claim 6 would be understood by one of ordinary skill in the art as excluding from the claimed extract that amount of secolanostane which adversely effects the ability of the extract to enhance the immunity of a mammal as explained in the specification as it would be interpreted by one of ordinary skill in the art.

The expression "substantially devoid of secolanostane" appears in original claim 6 and is discussed in the specification, at page 6 wherein it is stated that the present invention includes a Poria extract capable of enhancing immunity of a mammal, which is a claim limitation in claim 6. Part of the present invention is the discovery that the present of secolanostane has a deleterious effect on the enhancing of the immunity of

the extract of Poria containing lanostane as described in detail in the present specification which demonstrates the unexpected results of the presently claimed invention, see the comparative evidence contained in the working examples.

In addition, the Abstract of the Disclosure as originally filed and as amended and entered into this specification further describes the invention as a pharmaceutical composition which is used to enhance immunity of the human body. The composition contains potent components of lanostane compounds. A method is devised to obtain an extract from metabolite, sclerotium, or fermentation product of *Poria cocos* (Schw) Wolf. The extract contains 5-60% of the lanostane compounds by weight of the extract. The extract is devoid of secolanostane capable of inhibiting immunity development. Clearly, one of ordinary skill in the art knows that the amount of secolanostane which cannot be present is that amount which is capable of inhibiting immunity development of the extract of claim 6 and this aspect of the rejection should be withdrawn or reversed on appeal.

Claim 6 claims *"Poria* extract". In page 3, lines 18-20, to page 4, line 5, of the specification of the present application, Applicants describe "A chromatographic separation is used to separate constituents of the crude extract, which include a lanostane fraction and a secolanostane fraction. The lanostane fraction is obtained by using an eluent made of dichloromethane : methanol = 96:4, whereas the secolanostane fraction is obtained by using an eluent made of dichloromethane : methanol = 90:10 or 0:100. The position of the lanostane fraction is identified by the thin layer chromatography, which has a chromatographic value (Rf) being $\geq$ 0.1 when a developing solution of dichloromethane : methanol (96:4) is used. The chromatographic value of the secolanostane fraction is smaller than 0.1. By a silica gel column chromatograhpy, the lanostane fraction is separated into several lanostane compounds with an eluent made of dichloromethane : methanol alcohol = 97:3 to 95:5." From this description, Applicants provide a means to tell people skilled in the art how to separate the secolanostane fraction (Rf < 0.1) and the lanostane fraction (Rf $\geq$ 0.1). That is, Applicants particularly point out and distinctly claim the subject matter (i.e. *Poria*

extract) being substantially devoid of secolanostane by referring to the secolanostane fraction (Rf < 0.1) does not exist in the *Poria* extract claimed in claim 6.

Applicants do not intend to tell people skilled in the art that the *"Poria* extract" claimed in claim 6 contains "what specific amount of secolanostane could be present in the extract and still have the extract by considered 'substantially devoid of secolanostane'" Instead, applicants particularly point out and distinctly claim the *Poria* extract being substantially devoid of secolanostane, because the secolanostane fraction (Rf < 0.1) has been separated from the *Poria* extract claimed in claim 6 according to the technique disclosed in page 3, lines 18-20, to page 4, line 5, of the specification of the present application. Therefore, people skilled in the art would not question substantially devoid of secolanostane containing what amount of secolanostane could be present in the extract, but surely know the meaning of substantially devoid of secolanostane which has an adverse effect and is remove according to the technique disclosed in page 3, lines 18-20, to page 4, line 5 of the specification of the present application. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

The rejection of claims 7-10 do not stand or fall with the rejection of claims 6, 11, 12, and 13.

The term "low" in reference to the eluent polarity in claim 7, step d), is a relative term which is said to render the claim indefinite. The term "low" is said not to be defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Regarding the "low" polarity eluent, page 7, lines 11 and 12 of the specification state "It is recommended that the low polarity eluent is a mixed solvent containing dichloromethane and methanol...". The use of "It is recommended" in the definition of a low polarity eluent does not provide a closed definition for "low polarity." Thus, the specification does not provide a limiting definition for eluents that are considered to be "low polarity." Therefore, an artisan of ordinary skill could not reasonably ascertain what eluents are encompassed by this limitation. Accordingly, the

metes and bounds of the claim are unclear. Claims 8-10 are indefinite in that they depend from claim 7 and do not clarify this issue. It is noted that claim 11 does not appear in this rejection.

As to "the eluent having a low polarity" in claim 7, the Examiner pointed out page 7, lines 11 and 12 of the specification state "It is recommended that the low polarity eluent is a mixed solvent containing dichloromethane and methanol in a volumetric ratio of 96.5:3.5." Applicants most respectfully submit that "It is recommended" is stronger the -preferably- used in the patent literatures. Moreover, claim 11 provides a support that "It is recommended..." means "the eluent having a low polarity" is a mixed solvent containing dichloromethane and methanol in a volumetric ratio of 96.5:3.5. Thus the specification provides guidance to the meaning of the term as a specific composition is provided the polarity of which can be determined and this provides one of ordinary skill in the art with the necessary guidance as to the meaning of low polarity of the eluent used in this portion of the claim. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn or reversed on appeal.

IX. CONCLUSION

In view of the above arguments, and those previously presented in the brief on appeal; all of the rejections of the claims on appeal should be withdrawn or reversed. The application should be passed to issue.

Respectfully submitted,

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